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AF/1644/18

PATENT -- FEE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re: Application of PETER NASH ET AL	
Serial No.: 09/616,843	
Filed: July 14, 2000	Group Art Unit 1644
For: IMMUNOGEN ADHERENCE INHIBITOR AND METHOD OF MAKING AND USING SAME	Exr. P. Huynh
Case Docket No.: C150.12.3B	

LETTER

Commissioner for Patents
P.O. Box 1450
Washington, D.C. 20231

Sir:

Enclosed are:

1. The original and three (3) copies of Appellants' Brief; and

2. Brief fee of $160.

A small business statement is of record.

Respectfully submitted,

PETER NASH ET AL

By Richard O. Bartz

Richard O. Bartz
Registration No. 20,468
Southdale Office Centre
6750 France Avenue South, Suite 350
Edina, MN 55435-1983
(952) 920-3959

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on September 22, 2003.

Richard O. Bartz Reg No. 20,468
Name of applicant, assignee, or Registered Rep.

Richard O. Bartz
Signature

September 22, 2003
Date of Signature

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APPELLANT'S BRIEF UNDER 37 CFR 1.192

Commissioner for Patents
P.O. Box 1450
Washington, D.C. 20231

Sir:

This brief is in support of an appeal to the Board of Appeals from the final rejection dated April 22, 2003 of Claims 14 to 24 and 27 to 32. Copies of these claims are attached Appendix A.

1. REAL PARTY IN INTEREST

The real party in interest is Camas Incorporated, a Minnesota corporation having a place of business at 260 Derrynane Street, Le Center, Minnesota 56057, assignee of the invention and application.

2. RELATED APPEALS AND INTERFERENCES

None.

3. STATUS OF CLAIMS

Claims 14 to 24 and 27 to 32 are pending in the application.

Claims 14 to 24 and 27 to 32 have been rejected under 35 USC 112 and 35 USC 103(a).

No claims have been allowed.

4. STATUS OF AMENDMENTS FILED SUBSEQUENT TO FINAL REJECTION

Applicants have filed an amendment responsive to the new grounds of rejection of Claims 14, 15, 16, 27, 29 and 31 to overcome the 35 USC 112 rejections of these claims. The amendment reduces the issues to the 35 USC 103(a) rejection of the claims.

This amendment has not been considered by the Examiner and has not been entered in this application. Entry of the amendment does not present new issues or extensive review by the Examiner.

5. CONCISE SUMMARY OF THE INVENTION

This invention is directed to a method for the use of a microbial adherence inhibitor, in the form of chicken egg antibodies, for substantially preventing the attachment or adherence of colony-forming immunogens or haptens in the rumen and intestinal tract of host food animals. The method promotes the growth of food animals by improving feed conversion rates by decreasing the waste of dietary protein caused by the presence of certain colony-forming protein-wasting organisms in food animals.

Common bacterial immunogens which cause dramatic decreases in an animal's ability to utilize dietary protein include but are not limited to *Peptostreptococcus anaerobius*, *Clostridium aminophilum*, and *Clostridium sticklandii*. These organisms have been collectively primarily responsible for wasting up to 25 percent of the protein in cattle diets. This is a loss of as much as $25 billion annually to cattle producers and is especially apparent in grazing animals which are often deficient in protein, even though their protein intake appears to be adequate. As the host consumes protein in the diet, these deleterious organisms wastefully degrade the protein to ammonia which is converted to urea by the liver and kidneys and thus lost to the host when excreted as urine. These deleterious organisms also compete with beneficial organisms which the host needs for the efficient utilization of ammonia.

The young of chickens receive passive antibody protection through the store of antibodies placed

in the eggs in which they develop from the embryonic stage. Chickens, in particular, have the ability to "load up" their eggs as they are formed, with a very large supply of antibodies concentrated many fold over that which is present in the serum of the hen. In addition, chicken antibodies are much more stable and resistant to inactivation through digestion than mammalian antibodies, especially under adverse conditions. Once immunized the hen layers the unique IgY types immunogobulins in the yolk while depositing the common chicken IgM and IgA immunoglobulins in the albumin. The albumin helps resistance to the whole egg preparations and helps protect the avian antibodies. Furthermore, the large quantities of antibodies which are placed in eggs are much more exclusively those specific for the antigens to which the mother has most recently been exposed to and challenged by. This all results in the eggs of chickens being a most ideal source for large quantities of economically produced, highly specific and stable antibodies.

The method of a microbial adherence inhibitor for administration to host food animals to inhibit the adherence of colony-forming immunogens in the rumen and/or intestinal tracts of the food animals comprises first inoculating female chickens, in or about to reach their egg laying age, with the particular target immunogen. Then, after a period of time sufficient to permit the production in the bird of antibody to the targeted immunogen, the eggs laid by the birds are harvested. The total antibody-containing contents of the eggs are separated from the shells and dried. The dried separated egg antibody adherence inhibiting material may be stored or shipped for use when needed. The dried egg contents incorporating the antibody specific to the targeted immunogen is administered to the food animals by distributing the antibody material substantially uniformly throughout an animal feed and then supplying the resulting antibody-containing animal feed to the food animals. The antibody-containing animal feed is supplied to food animals during the normal finishing schedule prior to slaughter. The substantial prevention of colonization of the targeted organism in the rumen or intestinal tract of the animal will ultimately permit elimination of the organism from the animal. This repression of

colonization and elimination of the subject organisms will permit a significant decrease in wasteful degradation of the dietary protein fed to food production animals. In addition, the resulting decrease in competition to the non-ammonia producing organisms will further enhance the most efficient utilization of feed by the host.

The specification including the claims define methods of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of colony forming protein wasting immunogen in the rumen or intestinal tracts of the animals. The control of growth the colony forming wasting immunogen in the animal boosts feed efficiency and promotes growth of the animal. *Specification, page 7, lines 3 to 17.* The target protein wasting immunogen is from a class consisting of *P.anaerobius, C.sticklandii* and *C.aminophilium.* These immunogens are described in Examples 7, 8 and 9 on pages 17 and 18 of the specification. Examples 17, 18 and 19 relate to these immunogens. *Specification, pages 23 and 24.* Organisms that colonize in the rumen and digestive tract of a host animal must possess the capability of sticking or adhering to the rumen or intestinal tract surface in order to multiply and grow. *Specification, page 9, lines 15, 16.* The organism inhibitor of the invention interferes with adherence in a highly specific manner and on a cumulative basis prevent the targeted organism from multiplying, growing and colonizing. *Specification, page 9, lines 20-22.* Immunized hens layer unique IgY type immunoglobulins in the yolk of the egg and deposit IgM and IgA immunoglobulins in the albumin. *Specification, page 10, lines 21-23.* The albumin containing the IgM and IgA immunoglobulins helps resistance to the whole egg preparations and helps protect the avian antibodies. *Specification, page 11, line 1.* The organism inhibitor is the colonizing microorganism adhesion inhibitor that is chicken antibody, IgY immunoglobulins, which can very tightly bind to, coat, cover and obliterate adherins which attach themselves to their hosts. *Specification, page 10, lines 8-10.* The albumin IgM and IgA immunoglobulins bind

in the mucus tissue of the digestive tract of the antibody containing material thereby providing a longer sustaining effect of the antibody containing material. The IgM and IgA immunoglobulins have di-sulfide bonds that retain molecules together and provide larger antibody containing molecules. The larger antibody containing molecules are more effective in preventing adherence of the targeted immunogen in the digestive tract of the animal. Albumin is a protein that protects the activity of the IgY type immunoglobulins thereby increasing their active life in the intestinal tract. The result is that use of the antibody whole egg, yolk and albumin, mixed with animal feed or water substantially prevents adherence of the targeted immunogen in the digestive tract of the animal.

An alternate embodiment of the method includes the coating of carrier material with the whole egg yolk and albumin. The use of the carrier material helps distribute the entire contents of the eggs in a uniform method in the animal feed. The carrier material coated with the entire contents of the eggs makes it easier for mixing with standard animal feeds. *Example 21, page 24.* The feed mixed with the carrier material coated with entire contents of the eggs is supplied to the animals. The yolk and albumin immunoglobulins bind the protein-wasting immunogens on the mucus tissue of the rumen and digestive tract of the animal thereby preventing adherence of the protein-wasting immunogen in the intestinal tract of the animal. The coated carrier material increases the duration of the effectiveness of the immunoglobulins.

A further embodiment of the method includes the use of coating the mixed whole egg yolk and albumin on dry carrier material to dry the egg yolk and albumin. A separate drying process is not used prior to coating of the carrier material with the egg yolk and albumin. The elimination of a separate drying step increases the effectiveness of the immunoglobulins in inhibiting adherence immunogens in the intestinal tracts of animals.

6. CONCISE STATEMENT OF ALL ISSUES PRESENTED FOR REVIEW

A. Whether Claims 14-24 and 27-32 are unpatentable under 35 USC 112 because the specification does not enable a person skilled in the art to make and use the invention commensurate in scope with the claims and does not provide a written description of the method defined in the claims.

B. Whether Claims 14-24 and 27-32 are unpatentable under 35 USC 112 because they contain new matter.

C. Whether Claims 14, 15 and 16 are unpatentable under 35 USC 103(a) over U.S. Patent No. 5,080,895 (*Tokoro*) in view of *Krause et al*, U.S. Patent No. 5,585,098 (*Coleman*), and U.S. Patent No. 5,741,489 (*Pimentol*).

D. Whether Claims 17-24 are unpatentable under 35 USC 103(a) over U.S. Patent No. 5,080,895 (*Tokoro*) in view of *Krause et al*, U.S. Patent No. 5,585,098 (*Coleman*), U.S. Patent No. 5,741,489 (*Pimentol*) further in view of U.S. Patent No. 6,086,878 (*Adalsteinsson et al*) and U.S. Patent No. 4,166,867 (*Betz et al*).

E. Whether Claims 27-32 are unpatentable under 35 USC 103(a) over U.S. Patent No. 5,080,895 (*Tokoro*) in view of *Krause et al*, U.S. Patent No. 5,585,098 (*Coleman*), U.S. Patent No. 5,741,489 (*Pimentol*) further in view of U.S. Patent No. 6,086,878 (*Adalsteinsson et al*) and U.S. Patent No. 5,741,489 (*Betz et al*).

7. GROUPING OF CLAIMS

The claims fall into three groups.

Group I comprises Claims 14, 15 and 16. These claims define a method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of protein-wasting immunogens P antigen from P.anaerobius, CS antigen from C.sticklandi, and CA antigen from C.aminophilium. The method includes drying the antibody and albumin,

distributing the dried antibody and albumin substantially uniformly in animal feed or water, and supplying the resulting antibody and albumin and animal feed or water to food animals to prevent adherence of the immunogen in the intestinal tracts of animals thereby promoting the growth of the animals.

Group II comprise Claims 19-24. These claims include the subject matter of Claims 14, 15 and 16, the process of drying the antibody yolk and albumin and coating dry feed carrier material with the antibody yolk and albumin. The carrier material coated with the antibody yolk and albumin is distributed in animal feed or water and supplying the same to food animals.

Group III comprises Claims 25-32. These claims define a method of promoting the growth of food animals by decreasing the waste dietary protein caused by the presence of colony-forming protein-wasting immunogens in the rumen or intestinal tracts of food animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of animals to reduce the ability of the immunogen to multiply, the immunogens include P antigen from P.anaerobius, CS antigen from C.sticklandi and CA antigen from C.aminophilium. The method includes providing a dry feed carrier material, coating the dry feed carrier material with the antibody and albumin of the harvested eggs, distributing the carrier material coated with the antibody yolk and albumin substantially uniform in animal feed, and supplying the animal feed and carrier material coated with the antibody yolk and albumin to food animals to prevent adherence of the immunogens in the intestinal tracts of the animals thereby promoting growth of the animals. The entire yolk and albumin coats the dry feed carrier material which absorbs moisture from the yolk and albumin on the carrier material. The method does not include a separate step of drying the antibody yolk and albumin as required in the method of Claims 14, 15 and 16.

8. ARGUMENT

A. The specification of the application complies with the requirements of 35 USC 112.

Under 35 USC 112 ¶ 1 "the specification shall contain a written description of the invention and the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."

The specification clearly discloses applicants' method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of food animals.

The examiner has construed the requirements of 35 USC 112 to include any person skilled in the art "to make and use the invention commensurate in scope with these claims." *Office action 4/22/2003, page 4, lines 2-4.* This is not the requirement of 35 USC 112 ¶ 1. It is the specification, according to 35 USC 112 ¶ 1, that contains the written description to enable a person skilled in the art to make and use the same.

The specification describes the methods of Selection of Egg laying avian hens, pages 13-14; Preparation of Stock Culture, page 14; Preparation of A antigens for Immunogens, pages 14-15; Preparation of O antigens for immunogens, pages 15-16; Preparation of A antigen for immunogen, page 16-17; Preparation of P antigen for immunogen, pages 17-18; Preparation of CA antigen for immunogen, pages 18-19; Analysis of individual eggs and serum over time; pages 19-20; Immunization of chickens with immunogens, page 21-23; and Feeding of Cattle, pages 28-29. The specification contains a detailed description and best mod of applicants' process of promoting the growth of food animals, such as cattle, by decreasing the waste of

dietary protein caused by the presence of a protein-wasting immunogen in the rumen of intestinal tracts of the animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of the animals to reduce the ability of the immunogen to multiply. This description enables a person skilled in the art to make and use the subject method.

Under 35 USC 112 ¶ 2, "the specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which applicants regards as his invention." The examiner has not rejected the claims on the ground that they do not particularly point out and distinctly claim the subject matter of the invention.

B. Claims 14-24 and 27-32 do not contain new matter.

The examiner contends that these claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. *Office action 4/22/2003, page 6, ¶ 7.* This rejection is based upon the functional language of the claims that the IgY immunoglobulins bind to the protein-wasting immunogens. The specification states that the IgY immunoglobulins very tightly bind to, coat, cover and obliterate adherins which attach themselves to their hosts. *Page 10, lines 8-10.* The particular language as the "binding of IgY immunogens to protein-wasting immunogens is being increased by the IgM and IgA immunoglobulins". This function is supported by the disclosure that hen layers the unique IgY types immunglobulins in the yolk while depositing the common chicken IgM and IgA immunoglobulins in the albumin. The albumin helps resistance to the whole egg preparations and helps protect the avian antibodies. *Specification page 10, lines 21-23, page 11, line 1.* The whole egg preparation includes the IgY immunoglobins in the yolk and IgM and IgA immunoglobulins in the albumin. The term "helps" means aids, assists and encourages the protection of the avian antibodies. This language supports the increase in the finding of IgY

immunogens to the protein-wasting immunogens as more IgY immunogens are available to find to the protein-wasting immunogens.

The albumin IgM and IgA immunoglobulins increase binding in the mucus tissue of the digestive tract of the antibody containing material thereby providing a longer sustaining effect of the antibody containing material. The IgM and IgA immunoglobulins have di-sulfide bonds that retain molecules together and provide larger antibody containing molecules. The larger antibody containing molecules are more effective in preventing adherence of the targeted immunogen in the digestive tract of the animal. Albumin is a protein that protects the activity of the IgY type immunoglobulins thereby increasing their active life in the intestinal tract. The result is the use of the antibody whole egg, yolk and albumin, mixed with animal feed or water substantially prevents adherence of the targeted immongen in the digestive tract of the animal.

C. Claims 14, 15 and 16 are patentable in view of the teachings of *Tokoro, Krause et al, Coleman* and *Pimental.*

There are insufficient teachings of these combined references and no evidence of a motivating force which would impel one skilled in the art to practice the methods of Claims 14, 15 and 16. Claims 14, 15 and 16 stand rejected under 35 USC 103(a).

The test for determining obviousness of a claimed invention under 35 USC 103(a) is a four-part inquiring comprising (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the pertinent art; and (4) commercial considerations when such evidence is present. *Graham v. John Deere Co.*, 383 US 1 (1966); *Simmons Fastener Corp. v. Illinois Tool Works*, 222 USPQ 744 (Fed. Cir. 1984).

Obviousness cannot be properly established by locating references which describe various aspects of a patent applicant's invention without also showing evidence of a motivating force

which would impel one skilled in the art to do what the patent applicant has done. Simply because one can reconstruct an invention by combining isolated teachings of references is not a basis for an obviousness conclusion unless sufficient impetus can be shown which would have led one skilled in the art to combine the teachings to make the claimed invention. *Ex Parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. 1993).

It is well established that in deciding that a novel combination would have been obvious, there must be supporting teaching in the prior art. *In re Newell*, 13 USPQ2d 1248 (Fed. Cir. 1989). The prior art must provide a suggestion to make the combination with structure shown and claimed. *CR Bard Inc. v. M3 Systems, Inc.*, 48 USPQ2d 1225 (Fed. Cir. 1998).

The examiner has the burden under Section 103 to establish a *prima facie* case of obviousness. It can satisfy this burden *only* by showing some objective teaching in the prior art of that knowledge generally available to one of ordinary skill in the art which would lead that individual to combine the relevant teachings of the references. *In re Fine*, 5 USPQ2d 1596 (Fed. Cir. 1988).

1. Scope and content of the prior art.

The prior art comprises:

U.S. Patent No. 5,080,895 - Tokoro

Appl. Environ Microbial publication - Krause et al

U.S. Patent No. 5,585,098 - Coleman

U.S. Patent No. 5,741,489 - Pimental

Tokoro discloses a method of inhibiting diarrhea in animals with bird antibody IgY using the yolks, the albumin and the yolks of eggs. This method is related to the use of raw eggs by cattle herdpersons to treat scours (diarrhea in cattle caused by intestinal infection). *Tokoro* is directed to a specific antibody containing substance from eggs and method of production and use

thereof for the prevention and treatment of colibacillosis and diarrhea in animals. The antibody containing substance also is used as a nutrition supplement, and as an additive to food for animals. *Tokoro* does not provide a teaching of a method promoting the growth of food animals by binding IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens, P antigen from P.anaerobius, CS antigen from C.sticklandii, and CA antigen from C.aminophilium, by inhibiting the ability of these immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of the immunogens to multiply.

Krause et al discloses that amino acid degradation in the rumen of animals is nutritionally wasteful and produces more ammonia than the bacteria in the rumen can utilize. The excess ammonia is converted by the animal into urea and discharged into the environment as environmental pollution. The feed additive monensin decreases ammonia accumulation in the rumen. *Krause et al* discovered that monensin inhibited growth of P.anaerobius and C.sticklandii in the rumen of an animal but did not inhibit C.aminophilum. The result was the reduction in the amount of ammonia in the rumen and reduction of environmental pollution. There is no teaching that monensin prevents adherence of a targeted immunogen in the intestinal tract of an animal thereby inhibiting its colony growth. Monensin does not promote the growth of food animals by preventing targeted immunogens from adhering to the intestinal tract of an animal. U.S. Patent Nos. 3,501,568 and 3-797,32 are directed to the use of monesin for promoting growth and feed efficiency of food animals. Monensin can be toxic to some animals. Feed intake of the animals is reduced as monesin cannot be added to molases. *Specification, page 5, lines 4-12.*

Coleman discloses a method of using egg antibody preparations to prevent and treat mastitis in dairy cattle and milk producing animals. The preparation is limited to IgY antibodies

which are administered to the animal to lower milk somatic cell count. *Coleman* recognizes that the laying hen transfers all antibody isotypes found in the chicken to the egg, *i.e.*, IgY, IgM and IgA antibodies. The yolk contains only IgY while IgM and IgA are found only in the white. *Coleman* separates the yolk from the albumin. There is no teaching in *Coleman* to combine the yolk and albumin. The enhanced binding of IgY due to the IgM and IgA antibodies is not recognized by *Coleman.*

Pimentel discloses a method for increasing feed conversion efficiency in mammals with a diet containing an antibody produced using the enzyme urease as the antigen. *Pimental* states that chicken antibodies are generally known to protect the recipient against bacterial infections. No antibody has been shown to increase feed conversion efficient. *Col. 2, lines 59-63. Pimental* is limited to the use of an antibody against the enzyme urease to obtain increased feed utilization and body weight gain in animals. There is no teaching of a method of promoting the growth of food animals by binding IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens to inhibit the ability of the protein-wasting immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of the immunogens to multiply.

2. It is submitted that applicants' method of promoting the growth of food animals as defined in Claims 14, 15 and 16 are patentable in view of the individual and combined teachings of *Tokoro, Krause et al, Coleman* and *Pimentel.* There are no motivating directions or suggestions in these references that would impel one skilled in the art to produce the claimed method. There is no teaching of a method of promoting the growth of food animals by binding IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens to inhibit the ability of the protein-wasting immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of the immunogens to multiply.

D. Claims 17-24 are patentable in view of the teachings of *Tokoro, Krause et al, Coleman, Pemental, Addsteinsson et al* and *Betz*.

Claims 19-24 depend on Claims 14, 15 and 16. Claims 19-24 being dependent claims are to be contrued to incorporated by reference all the limitates of the claim to which it refers. 35 USC 112 ¶ 4. Claims 17 and 18 have been requested to be cancelled without prejudice.

Claims 19-24 include the process of proviciing a dry feed carrier material. The carrier material is coated with the entire dried contents of the eggs separated from the shells. The use of the carrier material helps distribute the entire contents of the eggs in a uniform method in the animal feed. The carrier material coated with the entire contents of the eggs makes it easier for mixing with standard feeds. *Example 21, page 24.* The feed mixed with the carrier material coated with entire contents of the eggs is supplied to the animals. The yolk IgY immunoglobulins combined with albumin IgM and IgA bind the protein-wasting immunogens on the mucus tissue of the rumen and digestive tract of the animal thereby preventing adherence of the protein-wasting immunogen in the intestinal tract of the animal. The albumin IgM and IgA promotes this binding action.

The remarks concerning *Tokoro, Krause et al, Coleman* and *Pemental* herein are applicable to Claims 17-24.

Adalsteinsson et al discloses a method of administering to animals an effective amount of a gastrointestinal neuro-modulator antibody to neutralize the neuro-modulator. The egg is dried into an egg powder. An example of drying is spray drying. The dried egg powder can be mixed with animal rations or sprayed directly onto food pellets. *Col. 9, lines 31-39.* This is a mixing process wherein dry powder is mixed with animal rations which include food pellets. Applicants coat a carrier material with the entire contents of the harvested eggs. The coated carrier material is distributed into the animal feed. The animal feed mixed with the coated carrier material is

supplied to the animals. The carrier materials are a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grain and beet pulp.

Betz et al discloses a method of making horse feed by mixing farinaceous material, proteinaceous material with fibrous materials, adding moisture, drying the mixture, and coating the combination with vegetable oil. The fibrous materials are selected from a group consisting of soy hulls, cottonseed hulls, and rice hulls. The fibrous materials provide structural strength to the feed pellets and effect stool normality. The fibrous materials are not coated with egg antibody.

Mixing dry egg powder to animal rations and coating a mixture of animal food with vegetable oil does not suggest to a person skilled in the art to coat a carrier material with IgY antibody as defined in Claims 19-24. Claims 19-24 are allowable over the combination of the subject prior art.

E. Claims 27-32 are patentable in view of the teachings of *Tokoro, Krause et al, Coleman, Pemental, Adalsteinsson et al* and *Betz et al.*

Claims 27-32 define the method of promoting growth of food animals by binding IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens, P antigen from P.annerobius, CS antigen from C.sticklandii and CA antigen from C.aminophilium, by inhibiting the ability of these immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of immunogens to multiply. The method does not include the step of drying the separated entire contents of the harvested eggs before the entire contents of the harvested eggs are coated on dry feed carrier material. The moisture of the entire harvested eggs on the dry feed carrier material is absorbed by the carrier material. This avoids the reduction of the effectiveness of IgY immunglobulins cause by the process of drying the entire contents of the harvested eggs.

The remarks concerning *Tokoro, Krause et al, Coleman* and *Pemental* herein are

applicable to Claims 25-32.

The references to *Adalsteinsson et al* and *Betz et al* are cited as teaching to coat any of the animal feed, such as soybean hulls, rice hulls, cottonseed hulls, corns and distilled dried grains. It is noted that these teachings do not utilize a dry feed carrier material to dry mixed egg yolks and albumin having yolk IgY immunoglobulins combined with albumin IgM and IgA immunoglobulins coated on the dry feed carrier. *Adalsteinsson et al*'s dried egg powder mixed with animal feed rations does not dry the egg powder. Also, spraying dried egg powder on food pellets in oil does not dry the egg powder.

Betz et al does not disclose drying of antibody yolk and albumin with soybean hulls, rice hulls or cottonseed hulls. The *Betz et al* animal feed is a mixture of materials including three hulls coated with a vegetable oil. The hulls are not used to dry any feed materials.

In view of the absence of a teaching of the claimed drying of antibody yolk and albumin with a dry feed carrier material by *Betz et al* and *Adalsteinsson et al*, it would not have been obvious to a persons skilled in the art to make and use the method defined in Claims 17 to 32. Claims 27 to 32 are allowable over the subject combination of prior art.

The reversal of the examiner's rejection as to Claims 14, 15, 16 and 19-32 is requested.

Respectfully submitted,

PETER NASH ET AL

By Richard O. Bartz

Richard O. Bartz
Registration No. 20,468
Southdale Office Centre
6750 France Avenue South, Suite 350
Edina, MN 55435-1983
(952) 920-3959

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on September 22, 2003.

Richard O. BARTZ Reg No. 30,468

Name of applicant, assignee, or Registered Rep.

Richard O. Bartz

Signature

September 22, 2003

Date of Signature

APPENDIX A

14. A method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of food animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply, said protein-wasting immunogen is P antigen from *P.anaerobius*, said method comprising:

A. Inoculating female birds, in or about to reach their egg laying age, with P antigen from *P.anaerobius*;

B. Allowing a period of time sufficient to permit the production in the birds and eggs laid by the birds of antibody in the eggs to P antigen from *P.anaerobius*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said harvested eggs from the egg shells;

E. Drying said separated entire contents of said harvested eggs;

F. Distributing said dried entire contents of said harvested eggs substantially uniformly in animal feed or water to provide antibody-containing animal feed or water; and

G. Supplying the resulting dried entire contents of said harvested eggs and animal feed or water to food animals whereby the IgY immunoglobulins bind to the protein-wasting immunogens to inhibit adherence of the protein-wasting immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

15. A method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of food animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply, said protein-wasting immunogen is CS antigen from *C.sticklandii*, said method comprising:

A. Inoculating female birds, in or about to reach their egg laying age, with CS antigen from *C.sticklandii*;

B. Allowing a period of time sufficient to permit the production in the birds and eggs laid by the birds of antibody in the eggs to CS antigen from *C.sticklandii*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said harvested eggs from the egg shells;

E. Drying said separated entire contents of said harvested eggs;

F. Distributing said dried entire contents of said harvested eggs substantially uniformly in animal feed or water; and

G. Supplying the resulting dried entire contents of said harvested eggs and animal feed or water to food animals whereby the IgY immunoglobulins bind to the protein-wasting immunogens to inhibit adherence of the protein-wasting immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

16. A method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of food animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply, said protein-wasting immunogen is CA antigen from *C.aminophilium*, said method comprising:

A. Inoculating female birds, in or about to reach their egg laying age, with CA antigen from *C.aminophilium*;

B. Allowing a period of time sufficient to permit the production in the birds and eggs laid by the birds of antibody in the eggs to CA antigen from *C.aminophilium*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said harvested eggs from the egg shells;

E. Drying said separated entire contents of said harvested eggs;

F. Distributing said dried entire contents of said harvested eggs substantially uniformly in animal feed or water; and

G. Supplying the resulting dried entire contents of said harvested eggs and animal feed or water to food animals whereby the IgY immunoglobulins bind to the protein-wasting immunogens to inhibit adherence of the protein-wasting immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

19. The method of Claim 14 including: providing a dry feed carrier material, drying said entire contents of said harvested eggs by coating the carrier material with said entire contents of said harvested eggs, distributing said carrier material coated with said entire contents of said harvested eggs in animal feed or water, and supplying the carrier material coated with said entire contents of said harvested eggs and animal feed or water to inhibit adherence of the immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

20. The method of Claim 19 wherein: providing a dry feed carrier material from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

21. The method of Claim 15 including: providing a dry feed carrier material, drying said entire contents of said harvested eggs by coating the carrier material with said entire contents of said harvested eggs, distributing said carrier material coated with said entire contents of said harvested eggs in animal feed or water, and supplying the carrier material coated with said entire contents of said harvested eggs and animal feed or water to inhibit adherence of the immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

22. The method of Claim 21 wherein: providing a dry feed carrier material from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

23. The method of Claim 16 including: providing a dry feed carrier material, drying said entire contents of said harvested eggs by coating the carrier material with said entire contents of said harvested eggs, distributing said carrier material coated with said entire contents of said harvested eggs in animal feed or water, and supplying the carrier material coated with said entire contents of said harvested eggs and animal feed or water to inhibit adherence of the immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

24. The method of Claim 23 wherein: providing a dry feed carrier material from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

27. A method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply, said protein-wasting immunogen is P antigen from *P.anaerobius*, said method comprising:

A. Inoculating female birds, in or about to reach their egg laying age, with P antigen from *P.anaerobius*;

B. Allowing a period of time sufficient to permit the production in the birds and eggs laid by the birds of antibody in the eggs to P antigen from *P.anaerobius*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said harvested eggs from the shells;

E. Providing a dry feed carrier material;

F. Coating said dry feed carrier material with the separated entire contents of said harvested eggs;

G. Distributing said carrier material coated with the entire contents of said harvested eggs substantially uniformly in animal feed; and

H. Supplying the resulting dry feed carrier material coated with the entire contents of said harvested eggs and animal feed to food animals whereby the IgY immunoglobulins bind to the protein-wasting immunogens to inhibit adherence of the immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

28. The method of Claim 27 wherein: providing a dry feed carrier material from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

29. A method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of food animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply, said protein-wasting immunogen is CS antigen from *C.sticklandii*, said method comprising:

A. Inoculating female birds, in or about to reach their egg laying age, with CS antigen from *C.sticklandii*;

B. Allowing a period of time sufficient to permit the production in the birds and eggs laid by the birds of antibody in the eggs to CS antigen from *C.sticklandii*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said harvested eggs from the egg shells;

E. Providing a dry feed carrier material;

F. Coating said dry feed carrier material with the separated entire contents of the harvested eggs;

G. Distributing said carrier material coated with the entire contents of the eggs substantially uniformly in animal feed; and

H. Supplying the resulting dry feed carrier material coated with the entire contents of the eggs and animal feed to food animals whereby the IgY immunoglobulins bind to the protein-wasting immunogens to inhibit adherence of the immunogen in the intestinal tracts of

the animals thereby promoting the growth of the animals.

30. The method of Claim 29 wherein: providing a dry feed carrier material from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

31. A method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of food animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply, said protein-wasting immunogen is CA antigen from *C.aminophilium*, said method comprising:

A. Inoculating female birds, in or about to reach their egg laying age, with CA antigen from *C.aminophilium*;

B. Allowing a period of time sufficient to permit the production in the birds and eggs laid by the birds of antibody in the eggs to CA antigen from *C.aminophilium*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said harvested eggs from the egg shells;

E. Providing a dry feed carrier material;

F. Coating said dry feed carrier material with the separated entire contents of the harvested eggs;

G. Distributing said carrier material coated with the entire contents of the eggs substantially uniformly in animal feed; and

H. Supplying the resulting dry feed carrier material coated with the entire contents of said harvested eggs and animal feed to food animals whereby the IgY

immunoglobulins bind to the protein-wasting immunogens to inhibit adherence of the immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

32. The method of Claim 31 wherein: providing a dry carrier from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled grains and beet pulp.

PATENT -- FEE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re: Application of PETER NASH ET AL	)	
Serial No.: 09/616,843	)	
Filed: July 14, 2000	)	Group Art Unit 1644
For: IMMUNOGEN ADHERENCE INHIBITOR AND METHOD OF MAKING AND USING SAME	)	Exr. P. Huynh
Case Docket No.: C150.12.3B	)	

APPELLANT'S BRIEF UNDER 37 CFR 1.192

Commissioner for Patents
P.O. Box 1450
Washington, D.C. 20231

Sir:

This brief is in support of an appeal to the Board of Appeals from the final rejection dated April 22, 2003 of Claims 14 to 24 and 27 to 32. Copies of these claims are attached Appendix A.

1. REAL PARTY IN INTEREST

The real party in interest is Camas Incorporated, a Minnesota corporation having a place of business at 260 Derrynane Street, Le Center, Minnesota 56057, assignee of the invention and application.

2. RELATED APPEALS AND INTERFERENCES

None.

3. STATUS OF CLAIMS

Claims 14 to 24 and 27 to 32 are pending in the application.

Claims 14 to 24 and 27 to 32 have been rejected under 35 USC 112 and 35 USC 103(a).

No claims have been allowed.

4. STATUS OF AMENDMENTS FILED SUBSEQUENT TO FINAL REJECTION

Applicants have filed an amendment responsive to the new grounds of rejection of Claims 14, 15, 16, 27, 29 and 31 to overcome the 35 USC 112 rejections of these claims. The amendment reduces the issues to the 35 USC 103(a) rejection of the claims.

This amendment has not been considered by the Examiner and has not been entered in this application. Entry of the amendment does not present new issues or extensive review by the Examiner.

5. CONCISE SUMMARY OF THE INVENTION

This invention is directed to a method for the use of a microbial adherence inhibitor, in the form of chicken egg antibodies, for substantially preventing the attachment or adherence of colony-forming immunogens or haptens in the rumen and intestinal tract of host food animals. The method promotes the growth of food animals by improving feed conversion rates by decreasing the waste of dietary protein caused by the presence of certain colony-forming protein-wasting organisms in food animals.

Common bacterial immunogens which cause dramatic decreases in an animal's ability to utilize dietary protein include but are not limited to *Peptostreptococcus anaerobius*, *Clostridium aminophilum*, and *Clostridium sticklandii*. These organisms have been collectively primarily responsible for wasting up to 25 percent of the protein in cattle diets. This is a loss of as much as $25 billion annually to cattle producers and is especially apparent in grazing animals which are often deficient in protein, even though their protein intake appears to be adequate. As the host consumes protein in the diet, these deleterious organisms wastefully degrade the protein to ammonia which is converted to urea by the liver and kidneys and thus lost to the host when excreted as urine. These deleterious organisms also compete with beneficial organisms which the host needs for the efficient utilization of ammonia.

The young of chickens receive passive antibody protection through the store of antibodies placed

in the eggs in which they develop from the embryonic stage. Chickens, in particular, have the ability to "load up" their eggs as they are formed, with a very large supply of antibodies concentrated many fold over that which is present in the serum of the hen. In addition, chicken antibodies are much more stable and resistant to inactivation through digestion than mammalian antibodies, especially under adverse conditions. Once immunized the hen layers the unique IgY types immunogobulins in the yolk while depositing the common chicken IgM and IgA immunoglobulins in the albumin. The albumin helps resistance to the whole egg preparations and helps protect the avian antibodies. Furthermore, the large quantities of antibodies which are placed in eggs are much more exclusively those specific for the antigens to which the mother has most recently been exposed to and challenged by. This all results in the eggs of chickens being a most ideal source for large quantities of economically produced, highly specific and stable antibodies.

The method of a microbial adherence inhibitor for administration to host food animals to inhibit the adherence of colony-forming immunogens in the rumen and/or intestinal tracts of the food animals comprises first inoculating female chickens, in or about to reach their egg laying age, with the particular target immunogen. Then, after a period of time sufficient to permit the production in the bird of antibody to the targeted immunogen, the eggs laid by the birds are harvested. The total antibody-containing contents of the eggs are separated from the shells and dried. The dried separated egg antibody adherence inhibiting material may be stored or shipped for use when needed. The dried egg contents incorporating the antibody specific to the targeted immunogen is administered to the food animals by distributing the antibody material substantially uniformly throughout an animal feed and then supplying the resulting antibody-containing animal feed to the food animals. The antibody-containing animal feed is supplied to food animals during the normal finishing schedule prior to slaughter. The substantial prevention of colonization of the targeted organism in the rumen or intestinal tract of the animal will ultimately permit elimination of the organism from the animal. This repression of

colonization and elimination of the subject organisms will permit a significant decrease in wasteful degradation of the dietary protein fed to food production animals. In addition, the resulting decrease in competition to the non-ammonia producing organisms will further enhance the most efficient utilization of feed by the host.

The specification including the claims define methods of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of colony forming protein wasting immunogen in the rumen or intestinal tracts of the animals. The control of growth the colony forming wasting immunogen in the animal boosts feed efficiency and promotes growth of the animal. *Specification, page 7, lines 3 to 17.* The target protein wasting immunogen is from a class consisting of *P.anaerobius, C.sticklandii* and *C.aminophilium.* These immunogens are described in Examples 7, 8 and 9 on pages 17 and 18 of the specification. Examples 17, 18 and 19 relate to these immunogens. *Specification, pages 23 and 24.* Organisms that colonize in the rumen and digestive tract of a host animal must possess the capability of sticking or adhering to the rumen or intestinal tract surface in order to multiply and grow. *Specification, page 9, lines 15, 16.* The organism inhibitor of the invention interferes with adherence in a highly specific manner and on a cumulative basis prevent the targeted organism from multiplying, growing and colonizing. *Specification, page 9, lines 20-22.* Immunized hens layer unique IgY type immunoglobulins in the yolk of the egg and deposit IgM and IgA immunoglobulins in the albumin. *Specification, page 10, lines 21-23.* The albumin containing the IgM and IgA immunoglobulins helps resistance to the whole egg preparations and helps protect the avian antibodies. *Specification, page 11, line 1.* The organism inhibitor is the colonizing microorganism adhesion inhibitor that is chicken antibody, IgY immunoglobulins, which can very tightly bind to, coat, cover and obliterate adherins which attach themselves to their hosts. *Specification, page 10, lines 8-10.* The albumin IgM and IgA immunoglobulins bind

in the mucus tissue of the digestive tract of the antibody containing material thereby providing a longer sustaining effect of the antibody containing material. The IgM and IgA immunoglobulins have di-sulfide bonds that retain molecules together and provide larger antibody containing molecules. The larger antibody containing molecules are more effective in preventing adherence of the targeted immunogen in the digestive tract of the animal. Albumin is a protein that protects the activity of the IgY type immunoglobulins thereby increasing their active life in the intestinal tract. The result is that use of the antibody whole egg, yolk and albumin, mixed with animal feed or water substantially prevents adherence of the targeted immunogen in the digestive tract of the animal.

An alternate embodiment of the method includes the coating of carrier material with the whole egg yolk and albumin. The use of the carrier material helps distribute the entire contents of the eggs in a uniform method in the animal feed. The carrier material coated with the entire contents of the eggs makes it easier for mixing with standard animal feeds. *Example 21, page 24.* The feed mixed with the carrier material coated with entire contents of the eggs is supplied to the animals. The yolk and albumin immunoglobulins bind the protein-wasting immunogens on the mucus tissue of the rumen and digestive tract of the animal thereby preventing adherence of the protein-wasting immunogen in the intestinal tract of the animal. The coated carrier material increases the duration of the effectiveness of the immunoglobulins.

A further embodiment of the method includes the use of coating the mixed whole egg yolk and albumin on dry carrier material to dry the egg yolk and albumin. A separate drying process is not used prior to coating of the carrier material with the egg yolk and albumin. The elimination of a separate drying step increases the effectiveness of the immunoglobulins in inhibiting adherence immunogens in the intestinal tracts of animals.

6. CONCISE STATEMENT OF ALL ISSUES PRESENTED FOR REVIEW

A. Whether Claims 14-24 and 27-32 are unpatentable under 35 USC 112 because the specification does not enable a person skilled in the art to make and use the invention commensurate in scope with the claims and does not provide a written description of the method defined in the claims.

B. Whether Claims 14-24 and 27-32 are unpatentable under 35 USC 112 because they contain new matter.

C. Whether Claims 14, 15 and 16 are unpatentable under 35 USC 103(a) over U.S. Patent No. 5,080,895 (*Tokoro*) in view of *Krause et al*, U.S. Patent No. 5,585,098 (*Coleman*), and U.S. Patent No. 5,741,489 (*Pimentol*).

D. Whether Claims 17-24 are unpatentable under 35 USC 103(a) over U.S. Patent No. 5,080,895 (*Tokoro*) in view of *Krause et al*, U.S. Patent No. 5,585,098 (*Coleman*), U.S. Patent No. 5,741,489 (*Pimentol*) further in view of U.S. Patent No. 6,086,878 (*Adalsteinsson et al*) and U.S. Patent No. 4,166,867 (*Betz et al*).

E. Whether Claims 27-32 are unpatentable under 35 USC 103(a) over U.S. Patent No. 5,080,895 (*Tokoro*) in view of *Krause et al*, U.S. Patent No. 5,585,098 (*Coleman*), U.S. Patent No. 5,741,489 (*Pimentol*) further in view of U.S. Patent No. 6,086,878 (*Adalsteinsson et al*) and U.S. Patent No. 5,741,489 (*Betz et al*).

7. GROUPING OF CLAIMS

The claims fall into three groups.

Group I comprises Claims 14, 15 and 16. These claims define a method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of protein-wasting immunogens P antigen from P.anaerobius, CS antigen from C.sticklandi, and CA antigen from C.aminophilium. The method includes drying the antibody and albumin,

distributing the dried antibody and albumin substantially uniformly in animal feed or water, and supplying the resulting antibody and albumin and animal feed or water to food animals to prevent adherence of the immunogen in the intestinal tracts of animals thereby promoting the growth of the animals.

Group II comprise Claims 19-24. These claims include the subject matter of Claims 14, 15 and 16, the process of drying the antibody yolk and albumin and coating dry feed carrier material with the antibody yolk and albumin. The carrier material coated with the antibody yolk and albumin is distributed in animal feed or water and supplying the same to food animals.

Group III comprises Claims 25-32. These claims define a method of promoting the growth of food animals by decreasing the waste dietary protein caused by the presence of colony-forming protein-wasting immunogens in the rumen or intestinal tracts of food animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of animals to reduce the ability of the immunogen to multiply, the immunogens include P antigen from P.anaerobius, CS antigen from C.sticklandi and CA antigen from C.aminophilium. The method includes providing a dry feed carrier material, coating the dry feed carrier material with the antibody and albumin of the harvested eggs, distributing the carrier material coated with the antibody yolk and albumin substantially uniform in animal feed, and supplying the animal feed and carrier material coated with the antibody yolk and albumin to food animals to prevent adherence of the immunogens in the intestinal tracts of the animals thereby promoting growth of the animals. The entire yolk and albumin coats the dry feed carrier material which absorbs moisture from the yolk and albumin on the carrier material. The method does not include a separate step of drying the antibody yolk and albumin as required in the method of Claims 14, 15 and 16.

8. ARGUMENT

A. The specification of the application complies with the requirements of 35 USC 112.

Under 35 USC 112 ¶ 1 "the specification shall contain a written description of the invention and the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."

The specification clearly discloses applicants' method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of food animals.

The examiner has construed the requirements of 35 USC 112 to include any person skilled in the art "to make and use the invention commensurate in scope with these claims." *Office action 4/22/2003, page 4, lines 2-4.* This is not the requirement of 35 USC 112 ¶ 1. It is the specification, according to 35 USC 112 ¶ 1, that contains the written description to enable a person skilled in the art to make and use the same.

The specification describes the methods of Selection of Egg laying avian hens, pages 13-14; Preparation of Stock Culture, page 14; Preparation of A antigens for Immunogens, pages 14-15; Preparation of O antigens for immunogens, pages 15-16; Preparation of A antigen for immunogen, page 16-17; Preparation of P antigen for immunogen, pages 17-18; Preparation of CA antigen for immunogen, pages 18-19; Analysis of individual eggs and serum over time; pages 19-20; Immunization of chickens with immunogens, page 21-23; and Feeding of Cattle, pages 28-29. The specification contains a detailed description and best mod of applicants' process of promoting the growth of food animals, such as cattle, by decreasing the waste of

dietary protein caused by the presence of a protein-wasting immunogen in the rumen of intestinal tracts of the animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of the animals to reduce the ability of the immunogen to multiply. This description enables a person skilled in the art to make and use the subject method.

Under 35 USC 112 ¶ 2, "the specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which applicants regards as his invention." The examiner has not rejected the claims on the ground that they do not particularly point out and distinctly claim the subject matter of the invention.

B. Claims 14-24 and 27-32 do not contain new matter.

The examiner contends that these claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. *Office action 4/22/2003, page 6, ¶ 7.* This rejection is based upon the functional language of the claims that the IgY immunoglobulins bind to the protein-wasting immunogens. The specification states that the IgY immunoglobulins very tightly bind to, coat, cover and obliterate adherins which attach themselves to their hosts. *Page 10, lines 8-10.* The particular language as the "binding of IgY immunogens to protein-wasting immunogens is being increased by the IgM and IgA immunoglobulins". This function is supported by the disclosure that hen layers the unique IgY types immunglobulins in the yolk while depositing the common chicken IgM and IgA immunoglobulins in the albumin. The albumin helps resistance to the whole egg preparations and helps protect the avian antibodies. *Specification page 10, lines 21-23, page 11, line 1.* The whole egg preparation includes the IgY immunoglobins in the yolk and IgM and IgA immunoglobulins in the albumin. The term "helps" means aids, assists and encourages the protection of the avian antibodies. This language supports the increase in the finding of IgY

immunogens to the protein-wasting immunogens as more IgY immunogens are available to find to the protein-wasting immunogens.

The albumin IgM and IgA immunoglobulins increase binding in the mucus tissue of the digestive tract of the antibody containing material thereby providing a longer sustaining effect of the antibody containing material. The IgM and IgA immunoglobulins have di-sulfide bonds that retain molecules together and provide larger antibody containing molecules. The larger antibody containing molecules are more effective in preventing adherence of the targeted immunogen in the digestive tract of the animal. Albumin is a protein that protects the activity of the IgY type immunoglobulins thereby increasing their active life in the intestinal tract. The result is the use of the antibody whole egg, yolk and albumin, mixed with animal feed or water substantially prevents adherence of the targeted immongen in the digestive tract of the animal.

C. Claims 14, 15 and 16 are patentable in view of the teachings of *Tokoro, Krause et al, Coleman* and *Pimental.*

There are insufficient teachings of these combined references and no evidence of a motivating force which would impel one skilled in the art to practice the methods of Claims 14, 15 and 16. Claims 14, 15 and 16 stand rejected under 35 USC 103(a).

The test for determining obviousness of a claimed invention under 35 USC 103(a) is a four-part inquiring comprising (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the pertinent art; and (4) commercial considerations when such evidence is present. *Graham v. John Deere Co.*, 383 US 1 (1966); *Simmons Fastener Corp. v. Illinois Tool Works*, 222 USPQ 744 (Fed. Cir. 1984).

Obviousness cannot be properly established by locating references which describe various aspects of a patent applicant's invention without also showing evidence of a motivating force

which would impel one skilled in the art to do what the patent applicant has done. Simply because one can reconstruct an invention by combining isolated teachings of references is not a basis for an obviousness conclusion unless sufficient impetus can be shown which would have led one skilled in the art to combine the teachings to make the claimed invention. *Ex Parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. 1993).

It is well established that in deciding that a novel combination would have been obvious, there must be supporting teaching in the prior art. *In re Newell*, 13 USPQ2d 1248 (Fed. Cir. 1989). The prior art must provide a suggestion to make the combination with structure shown and claimed. *CR Bard Inc. v. M3 Systems, Inc.*, 48 USPQ2d 1225 (Fed. Cir. 1998).

The examiner has the burden under Section 103 to establish a *prima facie* case of obviousness. It can satisfy this burden *only* by showing some objective teaching in the prior art of that knowledge generally available to one of ordinary skill in the art which would lead that individual to combine the relevant teachings of the references. *In re Fine*, 5 USPQ2d 1596 (Fed. Cir. 1988).

1. Scope and content of the prior art.

The prior art comprises:

U.S. Patent No. 5,080,895 - Tokoro

Appl. Environ Microbial publication - Krause et al

U.S. Patent No. 5,585,098 - Coleman

U.S. Patent No. 5,741,489 - Pimental

Tokoro discloses a method of inhibiting diarrhea in animals with bird antibody IgY using the yolks, the albumin and the yolks of eggs. This method is related to the use of raw eggs by cattle herdpersons to treat scours (diarrhea in cattle caused by intestinal infection). *Tokoro* is directed to a specific antibody containing substance from eggs and method of production and use

thereof for the prevention and treatment of colibacillosis and diarrhea in animals. The antibody containing substance also is used as a nutrition supplement, and as an additive to food for animals. *Tokoro* does not provide a teaching of a method promoting the growth of food animals by binding IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens, P antigen from P.anaerobius, CS antigen from C.sticklandii, and CA antigen from C.aminophilium, by inhibiting the ability of these immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of the immunogens to multiply.

Krause et al discloses that amino acid degradation in the rumen of animals is nutritionally wasteful and produces more ammonia than the bacteria in the rumen can utilize. The excess ammonia is converted by the animal into urea and discharged into the environment as environmental pollution. The feed additive monensin decreases ammonia accumulation in the rumen. *Krause et al* discovered that monensin inhibited growth of P.anaerobius and C.sticklandii in the rumen of an animal but did not inhibit C.aminophilum. The result was the reduction in the amount of ammonia in the rumen and reduction of environmental pollution. There is no teaching that monensin prevents adherence of a targeted immunogen in the intestinal tract of an animal thereby inhibiting its colony growth. Monensin does not promote the growth of food animals by preventing targeted immunogens from adhering to the intestinal tract of an animal. U.S. Patent Nos. 3,501,568 and 3-797,32 are directed to the use of monesin for promoting growth and feed efficiency of food animals. Monensin can be toxic to some animals. Feed intake of the animals is reduced as monesin cannot be added to molases. *Specification, page 5, lines 4-12.*

Coleman discloses a method of using egg antibody preparations to prevent and treat mastitis in dairy cattle and milk producing animals. The preparation is limited to IgY antibodies

which are administered to the animal to lower milk somatic cell count. *Coleman* recognizes that the laying hen transfers all antibody isotypes found in the chicken to the egg, *i.e.*, IgY, IgM and IgA antibodies. The yolk contains only IgY while IgM and IgA are found only in the white. *Coleman* separates the yolk from the albumin. There is no teaching in *Coleman* to combine the yolk and albumin. The enhanced binding of IgY due to the IgM and IgA antibodies is not recognized by *Coleman*.

Pimentel discloses a method for increasing feed conversion efficiency in mammals with a diet containing an antibody produced using the enzyme urease as the antigen. *Pimental* states that chicken antibodies are generally known to protect the recipient against bacterial infections. No antibody has been shown to increase feed conversion efficient. *Col. 2, lines 59-63*. *Pimental* is limited to the use of an antibody against the enzyme urease to obtain increased feed utilization and body weight gain in animals. There is no teaching of a method of promoting the growth of food animals by binding IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens to inhibit the ability of the protein-wasting immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of the immunogens to multiply.

2. It is submitted that applicants' method of promoting the growth of food animals as defined in Claims 14, 15 and 16 are patentable in view of the individual and combined teachings of *Tokoro, Krause et al, Coleman* and *Pimentel*. There are no motivating directions or suggestions in these references that would impel one skilled in the art to produce the claimed method. There is no teaching of a method of promoting the growth of food animals by binding IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens to inhibit the ability of the protein-wasting immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of the immunogens to multiply.

D. Claims 17-24 are patentable in view of the teachings of *Tokoro, Krause et al, Coleman, Pemental, Addsteinsson et al* and *Betz.*

Claims 19-24 depend on Claims 14, 15 and 16. Claims 19-24 being dependent claims are to be contrued to incorporated by reference all the limitates of the claim to which it refers. 35 USC 112 ¶ 4. Claims 17 and 18 have been requested to be cancelled without prejudice.

Claims 19-24 include the process of providing a dry feed carrier material. The carrier material is coated with the entire dried contents of the eggs separated from the shells. The use of the carrier material helps distribute the entire contents of the eggs in a uniform method in the animal feed. The carrier material coated with the entire contents of the eggs makes it easier for mixing with standard feeds. *Example 21, page 24.* The feed mixed with the carrier material coated with entire contents of the eggs is supplied to the animals. The yolk IgY immunoglobulins combined with albumin IgM and IgA bind the protein-wasting immunogens on the mucus tissue of the rumen and digestive tract of the animal thereby preventing adherence of the protein-wasting immunogen in the intestinal tract of the animal. The albumin IgM and IgA promotes this binding action.

The remarks concerning *Tokoro, Krause et al, Coleman* and *Pemental* herein are applicable to Claims 17-24.

Adalsteinsson et al discloses a method of administering to animals an effective amount of a gastrointestinal neuro-modulator antibody to neutralize the neuro-modulator. The egg is dried into an egg powder. An example of drying is spray drying. The dried egg powder can be mixed with animal rations or sprayed directly onto food pellets. *Col. 9, lines 31-39.* This is a mixing process wherein dry powder is mixed with animal rations which include food pellets. Applicants coat a carrier material with the entire contents of the harvested eggs. The coated carrier material is distributed into the animal feed. The animal feed mixed with the coated carrier material is

supplied to the animals. The carrier materials are a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grain and beet pulp.

Betz et al discloses a method of making horse feed by mixing farinaceous material, proteinaceous material with fibrous materials, adding moisture, drying the mixture, and coating the combination with vegetable oil. The fibrous materials are selected from a group consisting of soy hulls, cottonseed hulls, and rice hulls. The fibrous materials provide structural strength to the feed pellets and effect stool normality. The fibrous materials are not coated with egg antibody.

Mixing dry egg powder to animal rations and coating a mixture of animal food with vegetable oil does not suggest to a person skilled in the art to coat a carrier material with IgY antibody as defined in Claims 19-24. Claims 19-24 are allowable over the combination of the subject prior art.

E. Claims 27-32 are patentable in view of the teachings of *Tokoro, Krause et al, Coleman, Pemental, Adalsteinsson et al* and *Betz et al.*

Claims 27-32 define the method of promoting growth of food animals by binding IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens, P antigen from P.annerobius, CS antigen from C.sticklandii and CA antigen from C.aminophilium, by inhibiting the ability of these immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of immunogens to multiply. The method does not include the step of drying the separated entire contents of the harvested eggs before the entire contents of the harvested eggs are coated on dry feed carrier material. The moisture of the entire harvested eggs on the dry feed carrier material is absorbed by the carrier material. This avoids the reduction of the effectiveness of IgY immunglobulins cause by the process of drying the entire contents of the harvested eggs.

The remarks concerning *Tokoro, Krause et al, Coleman* and *Pemental* herein are

applicable to Claims 25-32.

The references to *Adalsteinsson et al* and *Betz et al* are cited as teaching to coat any of the animal feed, such as soybean hulls, rice hulls, cottonseed hulls, corns and distilled dried grains. It is noted that these teachings do not utilize a dry feed carrier material to dry mixed egg yolks and albumin having yolk IgY immunoglobulins combined with albumin IgM and IgA immunoglobulins coated on the dry feed carrier. *Adalsteinsson et al*'s dried egg powder mixed with animal feed rations does not dry the egg powder. Also, spraying dried egg powder on food pellets in oil does not dry the egg powder.

Betz et al does not disclose drying of antibody yolk and albumin with soybean hulls, rice hulls or cottonseed hulls. The *Betz et al* animal feed is a mixture of materials including three hulls coated with a vegetable oil. The hulls are not used to dry any feed materials.

In view of the absence of a teaching of the claimed drying of antibody yolk and albumin with a dry feed carrier material by *Betz et al* and *Adalsteinsson et al*, it would not have been obvious to a persons skilled in the art to make and use the method defined in Claims 17 to 32. Claims 27 to 32 are allowable over the subject combination of prior art.

The reversal of the examiner's rejection as to Claims 14, 15, 16 and 19-32 is requested.

Respectfully submitted,

PETER NASH ET AL

By Richard O. Bartz

Richard O. Bartz
Registration No. 20,468
Southdale Office Centre
6750 France Avenue South, Suite 350
Edina, MN 55435-1983
(952) 920-3959

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on September 22, 2003.

Richard O. BARTZ Reg No. 30,468

Name of applicant, assignee, or Registered Rep.

Richard O. Bartz

Signature

September 22, 2003

Date of Signature

APPENDIX A

14. A method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of food animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply, said protein-wasting immunogen is P antigen from *P.anaerobius*, said method comprising:

A. Inoculating female birds, in or about to reach their egg laying age, with P antigen from *P.anaerobius*;

B. Allowing a period of time sufficient to permit the production in the birds and eggs laid by the birds of antibody in the eggs to P antigen from *P.anaerobius*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said harvested eggs from the egg shells;

E. Drying said separated entire contents of said harvested eggs;

F. Distributing said dried entire contents of said harvested eggs substantially uniformly in animal feed or water to provide antibody-containing animal feed or water; and

G. Supplying the resulting dried entire contents of said harvested eggs and animal feed or water to food animals whereby the IgY immunoglobulins bind to the protein-wasting immunogens to inhibit adherence of the protein-wasting immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

15. A method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of food animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply, said protein-wasting immunogen is CS antigen from *C.sticklandii*, said method comprising:

A. Inoculating female birds, in or about to reach their egg laying age, with CS antigen from *C.sticklandii*;

B. Allowing a period of time sufficient to permit the production in the birds and eggs laid by the birds of antibody in the eggs to CS antigen from *C.sticklandii*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said harvested eggs from the egg shells;

E. Drying said separated entire contents of said harvested eggs;

F. Distributing said dried entire contents of said harvested eggs substantially uniformly in animal feed or water; and

G. Supplying the resulting dried entire contents of said harvested eggs and animal feed or water to food animals whereby the IgY immunoglobulins bind to the protein-wasting immunogens to inhibit adherence of the protein-wasting immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

16. A method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of food animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply, said protein-wasting immunogen is CA antigen from *C.aminophilium*, said method comprising:

A. Inoculating female birds, in or about to reach their egg laying age, with CA antigen from *C.aminophilium*;

B. Allowing a period of time sufficient to permit the production in the birds and eggs laid by the birds of antibody in the eggs to CA antigen from *C.aminophilium*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said harvested eggs from the egg shells;

E. Drying said separated entire contents of said harvested eggs;

F. Distributing said dried entire contents of said harvested eggs substantially uniformly in animal feed or water; and

G. Supplying the resulting dried entire contents of said harvested eggs and animal feed or water to food animals whereby the IgY immunoglobulins bind to the protein-wasting immunogens to inhibit adherence of the protein-wasting immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

19. The method of Claim 14 including: providing a dry feed carrier material, drying said entire contents of said harvested eggs by coating the carrier material with said entire contents of said harvested eggs, distributing said carrier material coated with said entire contents of said harvested eggs in animal feed or water, and supplying the carrier material coated with said entire contents of said harvested eggs and animal feed or water to inhibit adherence of the immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

20. The method of Claim 19 wherein: providing a dry feed carrier material from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

21. The method of Claim 15 including: providing a dry feed carrier material, drying said entire contents of said harvested eggs by coating the carrier material with said entire contents of said harvested eggs, distributing said carrier material coated with said entire contents of said harvested eggs in animal feed or water, and supplying the carrier material coated with said entire contents of said harvested eggs and animal feed or water to inhibit adherence of the immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

22. The method of Claim 21 wherein: providing a dry feed carrier material from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

23. The method of Claim 16 including: providing a dry feed carrier material, drying said entire contents of said harvested eggs by coating the carrier material with said entire contents of said harvested eggs, distributing said carrier material coated with said entire contents of said harvested eggs in animal feed or water, and supplying the carrier material coated with said entire contents of said harvested eggs and animal feed or water to inhibit adherence of the immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

24. The method of Claim 23 wherein: providing a dry feed carrier material from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

27. A method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply, said protein-wasting immunogen is P antigen from *P.anaerobius*, said method comprising:

A. Inoculating female birds, in or about to reach their egg laying age, with P antigen from *P.anaerobius*;

B. Allowing a period of time sufficient to permit the production in the birds and eggs laid by the birds of antibody in the eggs to P antigen from *P.anaerobius*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said harvested eggs from the shells;

E. Providing a dry feed carrier material;

F. Coating said dry feed carrier material with the separated entire contents of said harvested eggs;

G. Distributing said carrier material coated with the entire contents of said harvested eggs substantially uniformly in animal feed; and

H. Supplying the resulting dry feed carrier material coated with the entire contents of said harvested eggs and animal feed to food animals whereby the IgY immunoglobulins bind to the protein-wasting immunogens to inhibit adherence of the immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

28. The method of Claim 27 wherein: providing a dry feed carrier material from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

29. A method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of food animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply, said protein-wasting immunogen is CS antigen from *C.sticklandii*, said method comprising:

A. Inoculating female birds, in or about to reach their egg laying age, with CS antigen from *C.sticklandii*;

B. Allowing a period of time sufficient to permit the production in the birds and eggs laid by the birds of antibody in the eggs to CS antigen from *C.sticklandii*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said harvested eggs from the egg shells;

E. Providing a dry feed carrier material;

F. Coating said dry feed carrier material with the separated entire contents of the harvested eggs;

G. Distributing said carrier material coated with the entire contents of the eggs substantially uniformly in animal feed; and

H. Supplying the resulting dry feed carrier material coated with the entire contents of the eggs and animal feed to food animals whereby the IgY immunoglobulins bind to the protein-wasting immunogens to inhibit adherence of the immunogen in the intestinal tracts of

the animals thereby promoting the growth of the animals.

30. The method of Claim 29 wherein: providing a dry feed carrier material from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

31. A method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of food animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply, said protein-wasting immunogen is CA antigen from *C.aminophilium*, said method comprising:

A. Inoculating female birds, in or about to reach their egg laying age, with CA antigen from *C.aminophilium*;

B. Allowing a period of time sufficient to permit the production in the birds and eggs laid by the birds of antibody in the eggs to CA antigen from *C.aminophilium*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said harvested eggs from the egg shells;

E. Providing a dry feed carrier material;

F. Coating said dry feed carrier material with the separated entire contents of the harvested eggs;

G. Distributing said carrier material coated with the entire contents of the eggs substantially uniformly in animal feed; and

H. Supplying the resulting dry feed carrier material coated with the entire contents of said harvested eggs and animal feed to food animals whereby the IgY

immunoglobulins bind to the protein-wasting immunogens to inhibit adherence of the immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

32. The method of Claim 31 wherein: providing a dry carrier from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled grains and beet pulp.

PATENT -- FEE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re: Application of PETER NASH ET AL	)	
Serial No.: 09/616,843	)	
Filed: July 14, 2000	)	Group Art Unit 1644
For: IMMUNOGEN ADHERENCE INHIBITOR AND METHOD OF MAKING AND USING SAME	)	Exr. P. Huynh
Case Docket No.: C150.12.3B	)	

APPELLANT'S BRIEF UNDER 37 CFR 1.192

Commissioner for Patents
P.O. Box 1450
Washington, D.C. 20231

Sir:

This brief is in support of an appeal to the Board of Appeals from the final rejection dated April 22, 2003 of Claims 14 to 24 and 27 to 32. Copies of these claims are attached Appendix A.

1. REAL PARTY IN INTEREST

The real party in interest is Camas Incorporated, a Minnesota corporation having a place of business at 260 Derrynane Street, Le Center, Minnesota 56057, assignee of the invention and application.

2. RELATED APPEALS AND INTERFERENCES

None.

3. STATUS OF CLAIMS

Claims 14 to 24 and 27 to 32 are pending in the application.

Claims 14 to 24 and 27 to 32 have been rejected under 35 USC 112 and 35 USC 103(a).

No claims have been allowed.

4. STATUS OF AMENDMENTS FILED SUBSEQUENT TO FINAL REJECTION

Applicants have filed an amendment responsive to the new grounds of rejection of Claims 14, 15, 16, 27, 29 and 31 to overcome the 35 USC 112 rejections of these claims. The amendment reduces the issues to the 35 USC 103(a) rejection of the claims.

This amendment has not been considered by the Examiner and has not been entered in this application. Entry of the amendment does not present new issues or extensive review by the Examiner.

5. CONCISE SUMMARY OF THE INVENTION

This invention is directed to a method for the use of a microbial adherence inhibitor, in the form of chicken egg antibodies, for substantially preventing the attachment or adherence of colony-forming immunogens or haptens in the rumen and intestinal tract of host food animals. The method promotes the growth of food animals by improving feed conversion rates by decreasing the waste of dietary protein caused by the presence of certain colony-forming protein-wasting organisms in food animals.

Common bacterial immunogens which cause dramatic decreases in an animal's ability to utilize dietary protein include but are not limited to *Peptostreptococcus anaerobius*, *Clostridium aminophilum*, and *Clostridium sticklandii*. These organisms have been collectively primarily responsible for wasting up to 25 percent of the protein in cattle diets. This is a loss of as much as $25 billion annually to cattle producers and is especially apparent in grazing animals which are often deficient in protein, even though their protein intake appears to be adequate. As the host consumes protein in the diet, these deleterious organisms wastefully degrade the protein to ammonia which is converted to urea by the liver and kidneys and thus lost to the host when excreted as urine. These deleterious organisms also compete with beneficial organisms which the host needs for the efficient utilization of ammonia.

The young of chickens receive passive antibody protection through the store of antibodies placed

in the eggs in which they develop from the embryonic stage. Chickens, in particular, have the ability to "load up" their eggs as they are formed, with a very large supply of antibodies concentrated many fold over that which is present in the serum of the hen. In addition, chicken antibodies are much more stable and resistant to inactivation through digestion than mammalian antibodies, especially under adverse conditions. Once immunized the hen layers the unique IgY types immunogobulins in the yolk while depositing the common chicken IgM and IgA immunoglobulins in the albumin. The albumin helps resistance to the whole egg preparations and helps protect the avian antibodies. Furthermore, the large quantities of antibodies which are placed in eggs are much more exclusively those specific for the antigens to which the mother has most recently been exposed to and challenged by. This all results in the eggs of chickens being a most ideal source for large quantities of economically produced, highly specific and stable antibodies.

The method of a microbial adherence inhibitor for administration to host food animals to inhibit the adherence of colony-forming immunogens in the rumen and/or intestinal tracts of the food animals comprises first inoculating female chickens, in or about to reach their egg laying age, with the particular target immunogen. Then, after a period of time sufficient to permit the production in the bird of antibody to the targeted immunogen, the eggs laid by the birds are harvested. The total antibody-containing contents of the eggs are separated from the shells and dried. The dried separated egg antibody adherence inhibiting material may be stored or shipped for use when needed. The dried egg contents incorporating the antibody specific to the targeted immunogen is administered to the food animals by distributing the antibody material substantially uniformly throughout an animal feed and then supplying the resulting antibody-containing animal feed to the food animals. The antibody-containing animal feed is supplied to food animals during the normal finishing schedule prior to slaughter. The substantial prevention of colonization of the targeted organism in the rumen or intestinal tract of the animal will ultimately permit elimination of the organism from the animal. This repression of

colonization and elimination of the subject organisms will permit a significant decrease in wasteful degradation of the dietary protein fed to food production animals. In addition, the resulting decrease in competition to the non-ammonia producing organisms will further enhance the most efficient utilization of feed by the host.

The specification including the claims define methods of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of colony forming protein wasting immunogen in the rumen or intestinal tracts of the animals. The control of growth the colony forming wasting immunogen in the animal boosts feed efficiency and promotes growth of the animal. *Specification, page 7, lines 3 to 17.* The target protein wasting immunogen is from a class consisting of *P.anaerobius, C.sticklandii* and *C.aminophilium.* These immunogens are described in Examples 7, 8 and 9 on pages 17 and 18 of the specification. Examples 17, 18 and 19 relate to these immunogens. *Specification, pages 23 and 24.* Organisms that colonize in the rumen and digestive tract of a host animal must possess the capability of sticking or adhering to the rumen or intestinal tract surface in order to multiply and grow. *Specification, page 9, lines 15, 16.* The organism inhibitor of the invention interferes with adherence in a highly specific manner and on a cumulative basis prevent the targeted organism from multiplying, growing and colonizing. *Specification, page 9, lines 20-22.* Immunized hens layer unique IgY type immunoglobulins in the yolk of the egg and deposit IgM and IgA immunoglobulins in the albumin. *Specification, page 10, lines 21-23.* The albumin containing the IgM and IgA immunoglobulins helps resistance to the whole egg preparations and helps protect the avian antibodies. *Specification, page 11, line 1.* The organism inhibitor is the colonizing microorganism adhesion inhibitor that is chicken antibody, IgY immunoglobulins, which can very tightly bind to, coat, cover and obliterate adherins which attach themselves to their hosts. *Specification, page 10, lines 8-10.* The albumin IgM and IgA immunoglobulins bind

in the mucus tissue of the digestive tract of the antibody containing material thereby providing a longer sustaining effect of the antibody containing material. The IgM and IgA immunoglobulins have di-sulfide bonds that retain molecules together and provide larger antibody containing molecules. The larger antibody containing molecules are more effective in preventing adherence of the targeted immunogen in the digestive tract of the animal. Albumin is a protein that protects the activity of the IgY type immunoglobulins thereby increasing their active life in the intestinal tract. The result is that use of the antibody whole egg, yolk and albumin, mixed with animal feed or water substantially prevents adherence of the targeted immunogen in the digestive tract of the animal.

An alternate embodiment of the method includes the coating of carrier material with the whole egg yolk and albumin. The use of the carrier material helps distribute the entire contents of the eggs in a uniform method in the animal feed. The carrier material coated with the entire contents of the eggs makes it easier for mixing with standard animal feeds. *Example 21, page 24.* The feed mixed with the carrier material coated with entire contents of the eggs is supplied to the animals. The yolk and albumin immunoglobulins bind the protein-wasting immunogens on the mucus tissue of the rumen and digestive tract of the animal thereby preventing adherence of the protein-wasting immunogen in the intestinal tract of the animal. The coated carrier material increases the duration of the effectiveness of the immunoglobulins.

A further embodiment of the method includes the use of coating the mixed whole egg yolk and albumin on dry carrier material to dry the egg yolk and albumin. A separate drying process is not used prior to coating of the carrier material with the egg yolk and albumin. The elimination of a separate drying step increases the effectiveness of the immunoglobulins in inhibiting adherence immunogens in the intestinal tracts of animals.

6. CONCISE STATEMENT OF ALL ISSUES PRESENTED FOR REVIEW

A. Whether Claims 14-24 and 27-32 are unpatentable under 35 USC 112 because the specification does not enable a person skilled in the art to make and use the invention commensurate in scope with the claims and does not provide a written description of the method defined in the claims.

B. Whether Claims 14-24 and 27-32 are unpatentable under 35 USC 112 because they contain new matter.

C. Whether Claims 14, 15 and 16 are unpatentable under 35 USC 103(a) over U.S. Patent No. 5,080,895 (*Tokoro*) in view of *Krause et al*, U.S. Patent No. 5,585,098 (*Coleman*), and U.S. Patent No. 5,741,489 (*Pimentol*).

D. Whether Claims 17-24 are unpatentable under 35 USC 103(a) over U.S. Patent No. 5,080,895 (*Tokoro*) in view of *Krause et al*, U.S. Patent No. 5,585,098 (*Coleman*), U.S. Patent No. 5,741,489 (*Pimentol*) further in view of U.S. Patent No. 6,086,878 (*Adalsteinsson et al*) and U.S. Patent No. 4,166,867 (*Betz et al*).

E. Whether Claims 27-32 are unpatentable under 35 USC 103(a) over U.S. Patent No. 5,080,895 (*Tokoro*) in view of *Krause et al*, U.S. Patent No. 5,585,098 (*Coleman*), U.S. Patent No. 5,741,489 (*Pimentol*) further in view of U.S. Patent No. 6,086,878 (*Adalsteinsson et al*) and U.S. Patent No. 5,741,489 (*Betz et al*).

7. GROUPING OF CLAIMS

The claims fall into three groups.

Group I comprises Claims 14, 15 and 16. These claims define a method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of protein-wasting immunogens P antigen from P.anaerobius, CS antigen from C.sticklandi, and CA antigen from C.aminophilium. The method includes drying the antibody and albumin,

distributing the dried antibody and albumin substantially uniformly in animal feed or water, and supplying the resulting antibody and albumin and animal feed or water to food animals to prevent adherence of the immunogen in the intestinal tracts of animals thereby promoting the growth of the animals.

Group II comprise Claims 19-24. These claims include the subject matter of Claims 14, 15 and 16, the process of drying the antibody yolk and albumin and coating dry feed carrier material with the antibody yolk and albumin. The carrier material coated with the antibody yolk and albumin is distributed in animal feed or water and supplying the same to food animals.

Group III comprises Claims 25-32. These claims define a method of promoting the growth of food animals by decreasing the waste dietary protein caused by the presence of colony-forming protein-wasting immunogens in the rumen or intestinal tracts of food animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of animals to reduce the ability of the immunogen to multiply, the immunogens include P antigen from P.anaerobius, CS antigen from C.sticklandi and CA antigen from C.aminophilium. The method includes providing a dry feed carrier material, coating the dry feed carrier material with the antibody and albumin of the harvested eggs, distributing the carrier material coated with the antibody yolk and albumin substantially uniform in animal feed, and supplying the animal feed and carrier material coated with the antibody yolk and albumin to food animals to prevent adherence of the immunogens in the intestinal tracts of the animals thereby promoting growth of the animals. The entire yolk and albumin coats the dry feed carrier material which absorbs moisture from the yolk and albumin on the carrier material. The method does not include a separate step of drying the antibody yolk and albumin as required in the method of Claims 14, 15 and 16.

8. ARGUMENT

A. The specification of the application complies with the requirements of 35 USC 112.

Under 35 USC 112 ¶ 1 "the specification shall contain a written description of the invention and the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."

The specification clearly discloses applicants' method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of food animals.

The examiner has construed the requirements of 35 USC 112 to include any person skilled in the art "to make and use the invention commensurate in scope with these claims." *Office action 4/22/2003, page 4, lines 2-4.* This is not the requirement of 35 USC 112 ¶ 1. It is the specification, according to 35 USC 112 ¶ 1, that contains the written description to enable a person skilled in the art to make and use the same.

The specification describes the methods of Selection of Egg laying avian hens, pages 13-14; Preparation of Stock Culture, page 14; Preparation of A antigens for Immunogens, pages 14-15; Preparation of O antigens for immunogens, pages 15-16; Preparation of A antigen for immunogen, page 16-17; Preparation of P antigen for immunogen, pages 17-18; Preparation of CA antigen for immunogen, pages 18-19; Analysis of individual eggs and serum over time; pages 19-20; Immunization of chickens with immunogens, page 21-23; and Feeding of Cattle, pages 28-29. The specification contains a detailed description and best mod of applicants' process of promoting the growth of food animals, such as cattle, by decreasing the waste of

dietary protein caused by the presence of a protein-wasting immunogen in the rumen of intestinal tracts of the animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of the animals to reduce the ability of the immunogen to multiply. This description enables a person skilled in the art to make and use the subject method.

Under 35 USC 112 ¶ 2, "the specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which applicants regards as his invention." The examiner has not rejected the claims on the ground that they do not particularly point out and distinctly claim the subject matter of the invention.

B. Claims 14-24 and 27-32 do not contain new matter.

The examiner contends that these claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. *Office action 4/22/2003, page 6, ¶ 7.* This rejection is based upon the functional language of the claims that the IgY immunoglobulins bind to the protein-wasting immunogens. The specification states that the IgY immunoglobulins very tightly bind to, coat, cover and obliterate adherins which attach themselves to their hosts. *Page 10, lines 8-10.* The particular language as the "binding of IgY immunogens to protein-wasting immunogens is being increased by the IgM and IgA immunoglobulins". This function is supported by the disclosure that hen layers the unique IgY types immunglobulins in the yolk while depositing the common chicken IgM and IgA immunoglobulins in the albumin. The albumin helps resistance to the whole egg preparations and helps protect the avian antibodies. *Specification page 10, lines 21-23, page 11, line 1.* The whole egg preparation includes the IgY immunoglobins in the yolk and IgM and IgA immunoglobulins in the albumin. The term "helps" means aids, assists and encourages the protection of the avian antibodies. This language supports the increase in the finding of IgY

immunogens to the protein-wasting immunogens as more IgY immunogens are available to find to the protein-wasting immunogens.

The albumin IgM and IgA immunoglobulins increase binding in the mucus tissue of the digestive tract of the antibody containing material thereby providing a longer sustaining effect of the antibody containing material. The IgM and IgA immunoglobulins have di-sulfide bonds that retain molecules together and provide larger antibody containing molecules. The larger antibody containing molecules are more effective in preventing adherence of the targeted immunogen in the digestive tract of the animal. Albumin is a protein that protects the activity of the IgY type immunoglobulins thereby increasing their active life in the intestinal tract. The result is the use of the antibody whole egg, yolk and albumin, mixed with animal feed or water substantially prevents adherence of the targeted immongen in the digestive tract of the animal.

C. Claims 14, 15 and 16 are patentable in view of the teachings of *Tokoro, Krause et al, Coleman* and *Pimental.*

There are insufficient teachings of these combined references and no evidence of a motivating force which would impel one skilled in the art to practice the methods of Claims 14, 15 and 16. Claims 14, 15 and 16 stand rejected under 35 USC 103(a).

The test for determining obviousness of a claimed invention under 35 USC 103(a) is a four-part inquiring comprising (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the pertinent art; and (4) commercial considerations when such evidence is present. *Graham v. John Deere Co.*, 383 US 1 (1966); *Simmons Fastener Corp. v. Illinois Tool Works*, 222 USPQ 744 (Fed. Cir. 1984).

Obviousness cannot be properly established by locating references which describe various aspects of a patent applicant's invention without also showing evidence of a motivating force

which would impel one skilled in the art to do what the patent applicant has done. Simply because one can reconstruct an invention by combining isolated teachings of references is not a basis for an obviousness conclusion unless sufficient impetus can be shown which would have led one skilled in the art to combine the teachings to make the claimed invention. *Ex Parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. 1993).

It is well established that in deciding that a novel combination would have been obvious, there must be supporting teaching in the prior art. *In re Newell*, 13 USPQ2d 1248 (Fed. Cir. 1989). The prior art must provide a suggestion to make the combination with structure shown and claimed. *CR Bard Inc. v. M3 Systems, Inc.*, 48 USPQ2d 1225 (Fed. Cir. 1998).

The examiner has the burden under Section 103 to establish a *prima facie* case of obviousness. It can satisfy this burden *only* by showing some objective teaching in the prior art of that knowledge generally available to one of ordinary skill in the art which would lead that individual to combine the relevant teachings of the references. *In re Fine*, 5 USPQ2d 1596 (Fed. Cir. 1988).

1. Scope and content of the prior art.

The prior art comprises:

U.S. Patent No. 5,080,895 - Tokoro

Appl. Environ Microbial publication - Krause et al

U.S. Patent No. 5,585,098 - Coleman

U.S. Patent No. 5,741,489 - Pimental

Tokoro discloses a method of inhibiting diarrhea in animals with bird antibody IgY using the yolks, the albumin and the yolks of eggs. This method is related to the use of raw eggs by cattle herdpersons to treat scours (diarrhea in cattle caused by intestinal infection). *Tokoro* is directed to a specific antibody containing substance from eggs and method of production and use

thereof for the prevention and treatment of colibacillosis and diarrhea in animals. The antibody containing substance also is used as a nutrition supplement, and as an additive to food for animals. *Tokoro* does not provide a teaching of a method promoting the growth of food animals by binding IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens, P antigen from P.anaerobius, CS antigen from C.sticklandii, and CA antigen from C.aminophilium, by inhibiting the ability of these immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of the immunogens to multiply.

Krause et al discloses that amino acid degradation in the rumen of animals is nutritionally wasteful and produces more ammonia than the bacteria in the rumen can utilize. The excess ammonia is converted by the animal into urea and discharged into the environment as environmental pollution. The feed additive monensin decreases ammonia accumulation in the rumen. *Krause et al* discovered that monensin inhibited growth of P.anaerobius and C.sticklandii in the rumen of an animal but did not inhibit C.aminophilum. The result was the reduction in the amount of ammonia in the rumen and reduction of environmental pollution. There is no teaching that monensin prevents adherence of a targeted immunogen in the intestinal tract of an animal thereby inhibiting its colony growth. Monensin does not promote the growth of food animals by preventing targeted immunogens from adhering to the intestinal tract of an animal. U.S. Patent Nos. 3,501,568 and 3-797,32 are directed to the use of monesin for promoting growth and feed efficiency of food animals. Monensin can be toxic to some animals. Feed intake of the animals is reduced as monesin cannot be added to molases. *Specification, page 5, lines 4-12.*

Coleman discloses a method of using egg antibody preparations to prevent and treat mastitis in dairy cattle and milk producing animals. The preparation is limited to IgY antibodies

which are administered to the animal to lower milk somatic cell count. *Coleman* recognizes that the laying hen transfers all antibody isotypes found in the chicken to the egg, *i.e.*, IgY, IgM and IgA antibodies. The yolk contains only IgY while IgM and IgA are found only in the white. *Coleman* separates the yolk from the albumin. There is no teaching in *Coleman* to combine the yolk and albumin. The enhanced binding of IgY due to the IgM and IgA antibodies is not recognized by *Coleman.*

Pimentel discloses a method for increasing feed conversion efficiency in mammals with a diet containing an antibody produced using the enzyme urease as the antigen. *Pimental* states that chicken antibodies are generally known to protect the recipient against bacterial infections. No antibody has been shown to increase feed conversion efficient. *Col. 2, lines 59-63. Pimental* is limited to the use of an antibody against the enzyme urease to obtain increased feed utilization and body weight gain in animals. There is no teaching of a method of promoting the growth of food animals by binding IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens to inhibit the ability of the protein-wasting immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of the immunogens to multiply.

2. It is submitted that applicants' method of promoting the growth of food animals as defined in Claims 14, 15 and 16 are patentable in view of the individual and combined teachings of *Tokoro, Krause et al, Coleman* and *Pimentel.* There are no motivating directions or suggestions in these references that would impel one skilled in the art to produce the claimed method. There is no teaching of a method of promoting the growth of food animals by binding IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens to inhibit the ability of the protein-wasting immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of the immunogens to multiply.

D. Claims 17-24 are patentable in view of the teachings of *Tokoro, Krause et al, Coleman, Pemental, Addsteinsson et al* and *Betz.*

Claims 19-24 depend on Claims 14, 15 and 16. Claims 19-24 being dependent claims are to be contrued to incorporated by reference all the limitates of the claim to which it refers. 35 USC 112 ¶ 4. Claims 17 and 18 have been requested to be cancelled without prejudice.

Claims 19-24 include the process of providing a dry feed carrier material. The carrier material is coated with the entire dried contents of the eggs separated from the shells. The use of the carrier material helps distribute the entire contents of the eggs in a uniform method in the animal feed. The carrier material coated with the entire contents of the eggs makes it easier for mixing with standard feeds. *Example 21, page 24.* The feed mixed with the carrier material coated with entire contents of the eggs is supplied to the animals. The yolk IgY immunoglobulins combined with albumin IgM and IgA bind the protein-wasting immunogens on the mucus tissue of the rumen and digestive tract of the animal thereby preventing adherence of the protein-wasting immunogen in the intestinal tract of the animal. The albumin IgM and IgA promotes this binding action.

The remarks concerning *Tokoro, Krause et al, Coleman* and *Pemental* herein are applicable to Claims 17-24.

Adalsteinsson et al discloses a method of administering to animals an effective amount of a gastrointestinal neuro-modulator antibody to neutralize the neuro-modulator. The egg is dried into an egg powder. An example of drying is spray drying. The dried egg powder can be mixed with animal rations or sprayed directly onto food pellets. *Col. 9, lines 31-39.* This is a mixing process wherein dry powder is mixed with animal rations which include food pellets. Applicants coat a carrier material with the entire contents of the harvested eggs. The coated carrier material is distributed into the animal feed. The animal feed mixed with the coated carrier material is

supplied to the animals. The carrier materials are a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grain and beet pulp.

Betz et al discloses a method of making horse feed by mixing farinaceous material, proteinaceous material with fibrous materials, adding moisture, drying the mixture, and coating the combination with vegetable oil. The fibrous materials are selected from a group consisting of soy hulls, cottonseed hulls, and rice hulls. The fibrous materials provide structural strength to the feed pellets and effect stool normality. The fibrous materials are not coated with egg antibody.

Mixing dry egg powder to animal rations and coating a mixture of animal food with vegetable oil does not suggest to a person skilled in the art to coat a carrier material with IgY antibody as defined in Claims 19-24. Claims 19-24 are allowable over the combination of the subject prior art.

E. Claims 27-32 are patentable in view of the teachings of *Tokoro, Krause et al, Coleman, Pemental, Adalsteinsson et al* and *Betz et al.*

Claims 27-32 define the method of promoting growth of food animals by binding IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens, P antigen from P.annerobius, CS antigen from C.sticklandii and CA antigen from C.aminophilium, by inhibiting the ability of these immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of immunogens to multiply. The method does not include the step of drying the separated entire contents of the harvested eggs before the entire contents of the harvested eggs are coated on dry feed carrier material. The moisture of the entire harvested eggs on the dry feed carrier material is absorbed by the carrier material. This avoids the reduction of the effectiveness of IgY immunglobulins cause by the process of drying the entire contents of the harvested eggs.

The remarks concerning *Tokoro, Krause et al, Coleman* and *Pemental* herein are

applicable to Claims 25-32.

The references to *Adalsteinsson et al* and *Betz et al* are cited as teaching to coat any of the animal feed, such as soybean hulls, rice hulls, cottonseed hulls, corns and distilled dried grains. It is noted that these teachings do not utilize a dry feed carrier material to dry mixed egg yolks and albumin having yolk IgY immunoglobulins combined with albumin IgM and IgA immunoglobulins coated on the dry feed carrier. *Adalsteinsson et al*'s dried egg powder mixed with animal feed rations does not dry the egg powder. Also, spraying dried egg powder on food pellets in oil does not dry the egg powder.

Betz et al does not disclose drying of antibody yolk and albumin with soybean hulls, rice hulls or cottonseed hulls. The *Betz et al* animal feed is a mixture of materials including three hulls coated with a vegetable oil. The hulls are not used to dry any feed materials.

In view of the absence of a teaching of the claimed drying of antibody yolk and albumin with a dry feed carrier material by *Betz et al* and *Adalsteinsson et al*, it would not have been obvious to a persons skilled in the art to make and use the method defined in Claims 17 to 32. Claims 27 to 32 are allowable over the subject combination of prior art.

The reversal of the examiner's rejection as to Claims 14, 15, 16 and 19-32 is requested.

Respectfully submitted,

PETER NASH ET AL

By Richard O. Bartz

Richard O. Bartz
Registration No. 20,468
Southdale Office Centre
6750 France Avenue South, Suite 350
Edina, MN 55435-1983
(952) 920-3959

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on September 22, 2003.

Richard O. BARTZ Reg No. 30,468

Name of applicant, assignee, or Registered Rep.

Richard O. Bartz

Signature

September 22, 2003

Date of Signature

APPENDIX A

14. A method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of food animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply, said protein-wasting immunogen is P antigen from *P.anaerobius*, said method comprising:

A. Inoculating female birds, in or about to reach their egg laying age, with P antigen from *P.anaerobius*;

B. Allowing a period of time sufficient to permit the production in the birds and eggs laid by the birds of antibody in the eggs to P antigen from *P.anaerobius*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said harvested eggs from the egg shells;

E. Drying said separated entire contents of said harvested eggs;

F. Distributing said dried entire contents of said harvested eggs substantially uniformly in animal feed or water to provide antibody-containing animal feed or water; and

G. Supplying the resulting dried entire contents of said harvested eggs and animal feed or water to food animals whereby the IgY immunoglobulins bind to the protein-wasting immunogens to inhibit adherence of the protein-wasting immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

15. A method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of food animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply, said protein-wasting immunogen is CS antigen from *C.sticklandii*, said method comprising:

A. Inoculating female birds, in or about to reach their egg laying age, with CS antigen from *C.sticklandii*;

B. Allowing a period of time sufficient to permit the production in the birds and eggs laid by the birds of antibody in the eggs to CS antigen from *C.sticklandii*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said harvested eggs from the egg shells;

E. Drying said separated entire contents of said harvested eggs;

F. Distributing said dried entire contents of said harvested eggs substantially uniformly in animal feed or water; and

G. Supplying the resulting dried entire contents of said harvested eggs and animal feed or water to food animals whereby the IgY immunoglobulins bind to the protein-wasting immunogens to inhibit adherence of the protein-wasting immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

16. A method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of food animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply, said protein-wasting immunogen is CA antigen from *C.aminophilium*, said method comprising:

A. Inoculating female birds, in or about to reach their egg laying age, with CA antigen from *C.aminophilium*;

B. Allowing a period of time sufficient to permit the production in the birds and eggs laid by the birds of antibody in the eggs to CA antigen from *C.aminophilium*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said harvested eggs from the egg shells;

E. Drying said separated entire contents of said harvested eggs;

F. Distributing said dried entire contents of said harvested eggs substantially uniformly in animal feed or water; and

G. Supplying the resulting dried entire contents of said harvested eggs and animal feed or water to food animals whereby the IgY immunoglobulins bind to the protein-wasting immunogens to inhibit adherence of the protein-wasting immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

19. The method of Claim 14 including: providing a dry feed carrier material, drying said entire contents of said harvested eggs by coating the carrier material with said entire contents of said harvested eggs, distributing said carrier material coated with said entire contents of said harvested eggs in animal feed or water, and supplying the carrier material coated with said entire contents of said harvested eggs and animal feed or water to inhibit adherence of the immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

20. The method of Claim 19 wherein: providing a dry feed carrier material from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

21. The method of Claim 15 including: providing a dry feed carrier material, drying said entire contents of said harvested eggs by coating the carrier material with said entire contents of said harvested eggs, distributing said carrier material coated with said entire contents of said harvested eggs in animal feed or water, and supplying the carrier material coated with said entire contents of said harvested eggs and animal feed or water to inhibit adherence of the immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

22. The method of Claim 21 wherein: providing a dry feed carrier material from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

23. The method of Claim 16 including: providing a dry feed carrier material, drying said entire contents of said harvested eggs by coating the carrier material with said entire contents of said harvested eggs, distributing said carrier material coated with said entire contents of said harvested eggs in animal feed or water, and supplying the carrier material coated with said entire contents of said harvested eggs and animal feed or water to inhibit adherence of the immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

24. The method of Claim 23 wherein: providing a dry feed carrier material from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

27. A method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply, said protein-wasting immunogen is P antigen from *P.anaerobius*, said method comprising:

A. Inoculating female birds, in or about to reach their egg laying age, with P antigen from *P.anaerobius*;

B. Allowing a period of time sufficient to permit the production in the birds and eggs laid by the birds of antibody in the eggs to P antigen from *P.anaerobius*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said harvested eggs from the shells;

E. Providing a dry feed carrier material;

F. Coating said dry feed carrier material with the separated entire contents of said harvested eggs;

G. Distributing said carrier material coated with the entire contents of said harvested eggs substantially uniformly in animal feed; and

H. Supplying the resulting dry feed carrier material coated with the entire contents of said harvested eggs and animal feed to food animals whereby the IgY immunoglobulins bind to the protein-wasting immunogens to inhibit adherence of the immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

28. The method of Claim 27 wherein: providing a dry feed carrier material from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

29. A method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of food animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply, said protein-wasting immunogen is CS antigen from *C.sticklandii*, said method comprising:

A. Inoculating female birds, in or about to reach their egg laying age, with CS antigen from *C.sticklandii*;

B. Allowing a period of time sufficient to permit the production in the birds and eggs laid by the birds of antibody in the eggs to CS antigen from *C.sticklandii*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said harvested eggs from the egg shells;

E. Providing a dry feed carrier material;

F. Coating said dry feed carrier material with the separated entire contents of the harvested eggs;

G. Distributing said carrier material coated with the entire contents of the eggs substantially uniformly in animal feed; and

H. Supplying the resulting dry feed carrier material coated with the entire contents of the eggs and animal feed to food animals whereby the IgY immunoglobulins bind to the protein-wasting immunogens to inhibit adherence of the immunogen in the intestinal tracts of

the animals thereby promoting the growth of the animals.

30. The method of Claim 29 wherein: providing a dry feed carrier material from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

31. A method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of food animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply, said protein-wasting immunogen is CA antigen from *C.aminophilium*, said method comprising:

A. Inoculating female birds, in or about to reach their egg laying age, with CA antigen from *C.aminophilium*;

B. Allowing a period of time sufficient to permit the production in the birds and eggs laid by the birds of antibody in the eggs to CA antigen from *C.aminophilium*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said harvested eggs from the egg shells;

E. Providing a dry feed carrier material;

F. Coating said dry feed carrier material with the separated entire contents of the harvested eggs;

G. Distributing said carrier material coated with the entire contents of the eggs substantially uniformly in animal feed; and

H. Supplying the resulting dry feed carrier material coated with the entire contents of said harvested eggs and animal feed to food animals whereby the IgY

immunoglobulins bind to the protein-wasting immunogens to inhibit adherence of the immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

32. The method of Claim 31 wherein: providing a dry carrier from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled grains and beet pulp.